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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/462,972	01/14/2000	Joan Tellefsen Odell	BB1095	5723

7590 12/18/2003

E I du Pont Nemours and Company
Legal- Patents
Wilmington, DE 19898

EXAMINER	
BUI, PHUONG T	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 12/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/462,972	ODELL ET AL.	
	Examiner	Art Unit	
	Phuong T. Bui	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9/00,9/00*. 9/8/00, 9/29/00
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The Office acknowledges the receipt of Applicant's restriction election filed October 3, 2003. Applicant elects Group I and Invention A (SEQ ID NO:1 encoding SEQ ID NO:2) without traverse. Claims 11-22 are pending and are examined in the instant application. This restriction is made FINAL.

Sequence Listing

2. Applicant's CRF and paper sequence listing have been entered. However, upon examination of SEQ ID NO:1 and its corresponding amino acid sequence SEQ ID NO:2, it is unclear what region of SEQ ID NO:1 encodes SEQ ID NO:2. Clarification is required.

Information Disclosure Statement

3. Initialed and dated copies of Applicant's IDS form 1449, filed September 8, 2000 and September 29, 2000, are attached to the instant Office action.

Claim Rejections - 35 USC § 101 Utility

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 11-22 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility. Applicant asserted that the nucleotide sequence SEQ ID NO:1 encoding SEQ ID NO:2 has transcriptional coactivator activity.

Applicant states that SEQ ID NO:1 was isolated from soybean and encodes a SUG1 homolog. First of all, SEQ ID NO:1 does not appear to encode a complete protein. Even though

the protein encoded by SEQ ID NO:1 begins with methionine, the initiation codon, there is not a stop codon to indicate the end of the reading frame. The specification does not disclose that SEQ ID NO:2 is a complete protein. While a complete protein, such as an enzyme, inherently possesses region(s) essential for enzymatic activity, it is unclear as to whether SEQ ID NO:1 which encodes a partial protein would possess the regions essential for transcriptional coactivator activity. Applicant does not indicate whether SEQ ID NO:1 contains all the regions necessary for the asserted activity. Absent activity, it is unclear how one would use the claimed invention.

Secondly, in addition to Applicant's allegation that SEQ ID NO:1 encodes a SUG1 homolog, Applicant further states that SUG1 is associated with a variety of cellular activities, binds activation domains of transcription factors, and the mouse SUG1 may also play a role in protein degradation of abnormal proteins and naturally short lived proteins related to cell cycle control and metabolic regulation (specification, pages 1-2). It is noted here it is unclear how the mouse SUG1 is related to SEQ ID NO:1 of the instant application, as such is not disclosed. Applicant further asserts that SEQ ID NO:1 is an obvious target for manipulating gene regulation in eukaryotes, serves as a possible target for screening assays for crop protection chemicals and can be used to express SUG1 homologs to manipulate plant gene expression (specification, p. 2). Based upon Applicant's asserted utility for SEQ ID NO:1, Applicant's asserted utility fails to comply with current utility guidelines for the following reasons. First of all, Applicant's functional assignment for the encoded protein of SEQ ID NO:2 is based solely upon sequence alignment with a single prior art sequence. Applicant provided no empirical data to verify that SEQ ID NO:1 encodes a polypeptide having any transcriptional coactivator activity. While

empirical data is not required, sequence alignment is generally useful in placing a protein in a particular class but does not replace verification of function.

Thirdly, assuming arguendo that SEQ ID NO:2 has transcriptional coactivator activity, it is unclear how SEQ ID NO:2 can be used to achieve any real-world context of use. While regulation of gene expression of certain genes may be useful, e.g., herbicide resistance or male sterility, further guidance is necessary as to what gene(s) is being regulated, and how such regulation would ultimately result in a useful outcome. What real world use would binding the activation domains of transcription factors have, and how should the expression level of SEQ ID NO:1 be altered to affect such binding in a useful manner? Applicant further states that SEQ ID NO:1 is a possible target for screening assays for crop protection chemicals. While assaying for crop protection chemicals is important, no guidance is provided as to how SEQ ID NO:1 should be used to assay for crop protection chemicals. It is apparent that further research is required before the claimed polynucleotide would be of benefit to the public. However, the courts have decided that a utility which requires or constitutes carrying out further research to identify or reasonably confirm a "real world" context of use lacks substantial utility.

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point--where specific benefit exists in currently available form--there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." (Brenner v. Manson, 383 U.S. 519 (1966)).

Thus, while targeting a specified gene or assaying for crop protection chemicals would provide substantial benefit to the public, the claimed invention is not refined and developed to the point where specific benefit exists. Accordingly, the claimed invention lacks substantial asserted utility.

In addressing claims drawn to a sequence having 85-95% sequence identity to SEQ ID NO:1, since SEQ ID NO:1 and a polynucleotide encoding SEQ ID NO:2 lack utility for the reasons set forth above, sequences having less than 100% sequence identity or fragments of these sequences would also lack utility. Applicant should note that no working examples of a sequence having 85-95% sequence identity having transcriptional coactivator activity are set forth in Applicant's disclosure.

Additionally, there also is no well-established utility for SEQ ID NO:1 and a sequence encoding SEQ ID NO:2. SEQ ID NO:1 does not have a well-established utility for hybridization purposes because the encoded protein does not have utility for the reasons indicated above. Thus, for the reasons set forth, the claimed invention lacks utility under current utility guidelines. (see Utility Examination Guidelines published in Federal Register/ Vol. 66, No. 4/ Friday, January 5, 2001/ Notices; p. 1092-1099).

Claim Rejections - 35 USC § 112, first paragraph

5. Claims 11-22 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Furthermore, the recitation of "transcriptional coactivator activity" in the claims is not enabled because Applicant provided no guidance as to which transcriptional factor

SEQ ID NO:1 would coactivate, as there are at least as many transcriptional coactivators as there are transcriptional factors. Neither the transcriptional coactivator nor the transcriptional factor is specified. Thus one skilled in the art cannot make and use sequences having 85-95% sequence identity with SEQ ID NO:1 and having unspecified transcriptional coactivator activity without undue experimentation. Additionally, in claim 22, Applicant has not fully enabled "altering" as commensurate in scope with the claim. "Altering" encompasses both increasing and decreasing. However, the method steps set forth would express SEQ ID NO:1 and thus would increase the level of expression of the transcriptional coactivator. Furthermore, it is unclear how the same steps can be used to increase and decrease the level of protein expression. As neither the specification nor the state of the prior art provided no guidance as to how this can be achieved, Applicant has not enabled "altering" as commensurate in scope with the claim and without undue experimentation.

Claim Rejections - 35 USC § 112, first paragraph

6. Claims 11-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the **written description** requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to an isolated polynucleotide comprising a nucleotide sequence encoding a polypeptide having at least 85% sequence identity to SEQ ID NO:1. However, the translated amino acid sequence SEQ ID NO:2 appears to be only a partial sequence of a protein (see utility rejection above). Applicant also does not disclose in the specification that SEQ ID NO:1 encodes a complete protein or that SEQ ID NO:2 is a complete protein. Accordingly, the

Office has determined that SEQ ID NO:1, which encodes SEQ ID NO:2, is only a partial gene sequence and does not possess a complete open reading frame. However, the breadth of the claims reads upon a complete gene sequence which contains the SEQ ID NO:1 gene fragment. There is insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine the complete structure of a gene encoding the transcriptional activator protein, absent further guidance. Since the claimed genus, i.e, SEQ ID NO:1, encompasses undisclosed genes or genes yet to be discovered, the disclosed structural feature does not constitute a substantial portion of the claimed genus. Therefore, the disclosure of SEQ ID NO:1, or the nucleotide sequence encoding SEQ ID NO:2, does not provide an adequate description of the claimed genus, and in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of DNAs which comprise the nucleotide sequence of SEQ ID NO:1.

Moreover, the claims reciting 85-95% sequence identity lack adequate written description because Applicant does not disclose a representative number of species as encompassed by these claims. The claims encompass mutants and allelic variants and thus imply that structural variants exist in nature, yet no structural variant has been disclosed. The claims also encompass transcriptional coactivators from other species. The implication is that there is a gene and a protein other than that disclosed which exists in nature, but the structure thereof is not known. Applicant discloses a single sequence SEQ ID NO:1 isolated from soybean. Thus, there is insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine such mutants, allelic variants and transcriptional coactivators from other plants and organisms, absent further guidance. Accordingly, there is lack of adequate description to inform

a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/ Vol.66, No. 4/ Friday, January 5, 2001/ Notices; p. 1099-1111.

Remarks

7. No claim is allowed. SEQ ID Nos. 1 and 2 are free of the prior art. The closest prior art teaches a sequence having 80% sequence identity at the amino acid level with SEQ ID NO:2 (p. 17 of the specification).

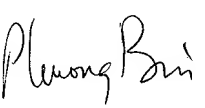
8. Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Bui whose telephone number is (703) 305-1996.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Phuong Bui
Primary Examiner
Group Art Unit 1638
December 14, 2003



PHUONG T. BUI
PRIMARY EXAMINER

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